MAYFIELD® Disposable and Reusable Titanium Skull Pins

510(k) Summary

K072208

SEP - 7 2007

Submitter's name and address:

Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, Ohio 45227 USA

Contact person and telephone number:

Helder A. Sousa
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
(609) 936- 6850

Date prepared:

August 7, 2007

Name of device:

Trade Name:	MAYFIELD® Disposable and Reusable Titanium Skull Pins
Common Name:	Skull Pins
Classification Name:	Neurological head holder (Skull Clamp)
Regulation Number:	21 CFR 882.4460
Product Code:	HBL

Substantial Equivalence:

The MAYFIELD® Disposable and Reusable Titanium Skull Pins are substantially equivalent in function and intended use to the MAYFIELD® Disposable Steel Skull Pins (K932860), MAYFIELD® Reusable Steel Skull Pins (pre-amendment), MAYFIELD® Radiolucent Disposable Skull Pins (K071458) and DORO Titanium Pins (K063494).

The MAYFIELD® Disposable and Reusable Titanium Skull Pins like the predicate devices are used in a skull clamp that is placed on the patient's head to hold the patient's head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired. The MAYFIELD® Disposable and Reusable Titanium Skull Pins like the predicate devices may be used in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary.

The MAYFIELD® Disposable and Reusable Titanium Skull Pins as the MAYFIELD® Radiolucent Disposable Skull Pins (K071458) and the DORO Titanium Pins (K063494) may be used in surgical procedures when Intra-Operative MR imaging of the patient is used.

Indications Use:

The MAYFIELD® Disposable and Reusable Titanium Skull Pins are intended for use with a MAYFIELD skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative MR imaging is used.

The MAYFIELD® Disposable and Reusable Titanium Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative MR imaging of the patient is used.

Device Description:

The MAYFIELD® Disposable and Reusable Titanium Skull Pins are available in two sizes, Adult and Child which are used with MAYFIELD® Skull Clamps that are applied to the patient's skull to hold their head and neck in a particular position during surgical procedures where rigid skeletal fixation is desired and intra-operative MR imaging is used.

In preparation for surgery three Titanium Skull Pins are installed in a MAYFIELD® Skull Clamp. Two Titanium Skull Pins are inserted in the Rocker Arm side of the Clamp and a single Titanium Skull Pin is inserted on the opposite side.

The MAYFIELD® Disposable and Reusable Titanium Skull Pins will be used during open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative MR imaging of the patient is used.

Conclusion:

The MAYFIELD® Disposable and Reusable Titanium Skull Pins are substantially equivalent to the MAYFIELD® Disposable Steel Skull Pins (K932860), MAYFIELD® Reusable Steel Skull Pins (pre-amendment), MAYFIELD® Radiolucent Disposable Skull Pins (K071458) and DORO® Skull Pins (K063494). The MAYFIELD® Disposable and Reusable Titanium Skull Pins are similar to the predicate devices in the intended use, the fundamental scientific technology of the device, and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences corpration
% Helder A. Sousa
Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, New Jersey 08536

SEP - 7 2007

Re: K072208
Trade/Device Name: MAYFIELD® Disposable and Reusable Titanium Skull Pins
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: August 7, 2007
Received: August 8, 2007

Dear Helder A. Sousa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

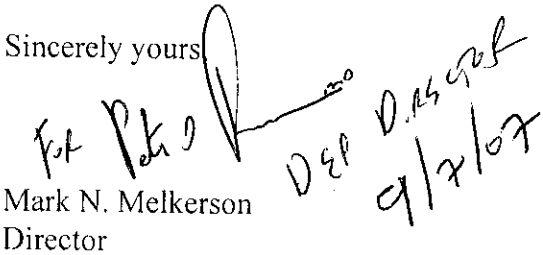
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072208

Device Name: MAYFIELD® Disposable and Reusable Titanium Skull Pins

Indications For Use:

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The MAYFIELD® Disposable and Reusable Titanium Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative MR imaging of the patient is used.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K072208